REMARKS

Claims 1-28 are pending in the application.

Claims 11-21 have been allowed. Claim 29 has been added and generally corresponds to claim 11, but with a broader construction of the clip chamber.

Claims 4-6 stand objected to but would be allowed if rewritten in independent form. The Examiner is asked to clarify the status of claim 6, as it is indicated as both objected to and rejected.

Claims 1-3, and 6 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,156,609 to Nakao et al. The applicant respectfully traverses the Examiner's rejection for the following reasons.

Nakao discloses spring biased staples which are biased into an open position and which include locking structure 204, 206 extending between the legs of the staples to lock the legs in a closed position. Movement of the legs against their bias does not 'deform' the staple as required by claim 1, but rather biases the legs against the spring force. Therefore Nakao fails to teach claim 1.

Further, claim 2 requires clamping first and second sections of tissue before advancing respective first and second staples. Nakao fails to teach "clamping . . . tissue before advancing" clips. In Nakao the staple is held in the jaws and applied to the tissue

simultaneously with clamping the tissue. In fact, Nakao fails to teach clamping tissue before "advancing" a first clip because the first staple must already be in the jaws before the jaws are initially opened.

Claim 3 requires that the first arm of the clip extends "into a deformable retainer" (i.e., extends to become a deformable retainer) which is bent during the "deforming" step. The Examiner states that he considers element 200 to meet this limitation. This is not understood. Element 200 is a jaw portion of the staple instrument. It is not part of the Nakao staple. It is not a retainer. It is not deformed. No portion of a leg of the Nakao staple extends into and becomes a retainer. The locking structure depends from central portions of legs.

For the foregoing reasons, Nakao fails to anticipates the claims.

With respect to claims 7-10, the Examiner states these claims are obvious over Nakao . The Examiner acknowledges that Nakao is silent as to the pushing force for advancing 'clips', but believes it would have been within the purview of one with ordinary skill in the art to advance Nakao's 'clips' with the pushing force limitations recited. The applicant respectfully traverses the Examiner's rejection for the following reasons.

In distinction from the Nakao instrument and methodology (and also the Hooven instrument and method discussed below), in the instrument and method of the invention,

the jaws are clamped about tissue prior to being loaded with a clip. Then, a clip is advanced via the pushing force through the jaws over clamped tissue. As the clip is pushed over tissue in a longitudinal direction, the pushing force must be substantial, on the order of the forces claimed.

In Nakao, the staples are not advanced over tissue via any "pushing force". Rather, the jaws of the instrument are open, and the staples are applied in the similar to taking a 'bite' into the tissue and then clamping the staples closed on the tissue. Pushing force is not at all required for application of a staple. The only pushing force is for advancement of another staple into the empty closed jaws in anticipation of subsequent staple application. This does not require any substantial pushing force within the limits of the claims. As such, there is no motivation to one skilled in the art to advance a staple in Nakao in accord with the claimed pushing force.

The applicant appreciates that the PTO lacks the ability to test the inventions submitted. Nevertheless, none of the art cited by the Examiner to reject the claims includes structure capable of effecting pushing force in excess of what is commonly known in the prior art. As discussed in the Specification,

> C. Paul Swain, MD, a recognized expert in endoscopic instruments and particularly endoscopic stapling devices, has stated that "[i]t is hard to exert more than 200g of force on the tissue when pushing . . .. This fact is of course one feature that makes intervention at flexible endoscopy relatively safe". *See* C. Paul Swain, "What Endoscopic Accessories Do We Really Need?", Emerging Technologies in Gastrointestinal Endoscopy, *Gastrointest. Endosc.*, Vol. 7, No. 2, pp. 313-330 (April 1997). Yet, a pushing force substantially greater than 200g is required to push a clip over compressed tissue. In fact, it is believed a force in excess of 500 grams (1.1 lbs) is required for a satisfactory instrument, and

> substantially greater forces, e.g., in excess of 1500 grams (3.3 lbs) would be desirable. (Spec. at page 2, line 24 – page 3, line 12.)

Nakao does not include any structure to overcome this recognized limitation in the prior art, and in view of the operation of Nakao there is no motivation to provide Nakao with such structure. Therefore, the limitations of claims 7-10 are not suggested by Nakao.

Claims 22-28 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 5,383,880 to Hooven. The applicant respectfully traverses the Examiner's rejection for the following reasons.

Claim 22 requires an inner member distally relative to an outer tubular member such that a relatively distal force of at least 500 grams is provided at the distal end of the inner member. Hooven fails to teach or suggest the claimed "relatively distal force of at least 500 grams is provided at said distal end of said inner member." The clip in Hooven is provided in the jaws prior to clamping down on tissue. The only distal force required in Hooven is for an unformed clip to be advanced into an empty set of jaws. The arguments advanced above with respect to Nakao apply equally as well with respect to Hooven. Further, in Hooven there is no motivation to modify the device to operate in accord with the claimed force.

Claims 26 and 27 require "providing a *compressive force to said [outer] tubular member* when moving said inner member distally relative to said outer tubular member."

This is not shown or suggested by Hooven and the Examiner has not addressed the limitation.

Claim 28 requires providing an instrument with "a flexible *coil* outer tubular member", and operating the handle "to create a tensile force of at least 500 grams at said distal end of said outer tubular member". Hooven fails to teach or suggest either of the coil or the creation of the *required tensile force at the distal end of the outer tubular member.*

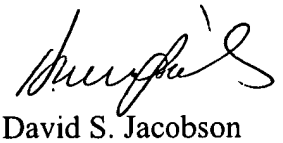
For the foregoing reasons, claims 22-28 are not obvious in view of Hooven and should be indicated as allowable.

Claims 30 and 31 have been added to more completely claim the invention. In claim 30, the deforming of a clip is specifically stated to be plastic. In Nakao, the staple has a spring bias construction and movement of the resilient legs does not cause plastic deformation thereof. That is, release of the lock holding the legs together will cause the legs to spring apart. In distinction, in claim 30, once the clip is deformed the deformation is permanent. Nakao fails to teach or suggest this limitation. Therefore, claim 30 is allowable over Nakao.

In light of all of the above, it is submitted that all claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain

outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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May 11, 2004